

STATE OF ISRAEL

Ministry of Agriculture and Rural Development,
Veterinary Services and Animal Health, P.O.B 12, Beit-Dagan, 50250.

December 20, 2000

Mr. Mark Manis
International Policy Division, Office of Policy
Program Development and Evaluation
F.S.I.S., USDA
Room 341-E, Jamie L. Whitten Federal Building
Washington D.C. 20250
U.S.A.

**Re.: FSIS audit report on the veterinary supervision system in plants approved for export: FSIS
Auditor's Report of October 12, 2000.**

Dear Mr. Manis,

Following please find the comments of the Israel Veterinary Services on the subject report.

Verification of the HACCP system in the plants

- 1) In the month of September the Israel Veterinary Services required all supervisory veterinarians in plants approved for export to participate in a workshop which was wholly devoted to processes for verification of HACCP systems.

In the course of the workshop the following topics were learned:

- a. The importance of the HACCP system in the reduction and prevention of health hazards in food.
 - b. Hazard identification in the production process.
 - c. The identification and characterization of critical control points in the production process.
 - d. Ways to determine the critical limits of the critical control points.
 - e. Determination of the inspection methods at the critical control points.
 - f. Documentation of the HACCP system
 - g. Determination of methods and procedures for verification of the effectiveness of the HACCP system.
 - h. Periodic "validation and evaluation" processes of the HACCP system.
- 2) During the month of August, each veterinarian received a procedure sheet which listed the stages of the HACCP verification procedure to be employed by the supervisory veterinarian. The procedures list is attached as Annex A. updated verification procedures according to FSIS requirements were introduced in October 2000.
 - 3) **Fecal Contamination (zero tolerance)**
Following receipt of the audit results, the HACCP programs in the certified plants were changed and new verification procedures were introduced to the production line as required by the auditor.

STATE OF ISRAEL


Ministry of Agriculture and Rural Development,
Veterinary Services and Animal Health, P.O. B 12, Beit-Dagan, 50250.

- 4) Examination of critical control point records prior to marketing of processed product
In conjunction with the auditor, it was determined that the pre-marketing review, follow-up, and supervision at critical control points would be performed first solely on products intended for the U.S. market. Accordingly, new procedures were introduced. The forms and records are now reviewed as required.
- 5) Intralaboratory check samples program
Attached please find the response to the auditor's comments, prepared by Dr. S. Sobak, head of the National Residue Control Laboratory.

Finally, I would like to take this opportunity to thank your auditor for his professional comments, which helped us to improve our supervision of the hygiene of poultry products in Israel. As in the past, the Israel Veterinary Services will continue to implement all necessary measures to safeguard the health and hygiene of meat products, and maintain Israel's position as an exporter of poultry products to the United States.

With sincere best wishes for the holiday season.

Sincerely yours,



Dr. E. Nili
Director

Control of Animal Products

Cc: Dr. O. Nir, (Markusfeld). BVSc, MRCVS
Director, Veterinary Services and Animal Health,
Agricultural Attache, U.S. Embassy, Tel-Aviv

Dr. T. Friedgut,
Office of Agricultural Affairs,
American Embassy, Tel-Aviv

STATE OF ISRAEL

Ministry of Agriculture and Rural Development,
Veterinary Services and Animal Health, P.O.B 12, Beit-Dagan, 50250.

ANNEX A

Procedure Sheet	3-2000	01/08/2000
-----------------	--------	------------

Verification of the HACCP System in Animal Food Production Plants Authorized for Export

1. Background

In order to reduce the health hazards involved in the manufacture and/or processing of animal food products and the consequent potential harm to consumer health, health services in the western world have defined the requirements for establishing an HACCP (Hazard Analysis and Critical Control Points) system for every approved plant. The plan is based on an analysis of the hazards and critical control points in the manufacturing process.

The HACCP approach is an efficient and systematic control system for the manufacturing process that will enable identification of anticipated hazards to consumer health. This approach also enables the evaluation of hazards and implementation of the actions required for preventing product contamination by biological, chemical or physical factors.

The health authorities supervising the hygiene level of food products in the USA and EU have stipulated in their legislation the obligation of establishing the HACCP system in local plants that process animal food-products. At the same time, a target date was set for the overseas implementation of the system in plants requesting to export products into their domains. Israel, as an approved animal products exporting country, was required to report regarding the operation of HACCP systems in all its authorized export plants no later than January 25, 1999.

A project manager, whose task is to provide training and inspection of animal product export plants, has been working for the Department for Inspection of Animal Products since February 1998.

The first stage consisted of establishing a system infrastructure, based on the collected HACCP principles and their transformation into applicable requirements, followed by adopting these principles by the plants. The plant management was given the responsibility of structuring the HACCP plans. The plans were presented to and checked by the project manager in collaboration with experts in the Department for Inspection of Animal Products. Plans that complied with the requirements were approved, and the plants were requested to operate accordingly.

Once the approved plan is in operation, the project manager undertakes a certifying examination, aimed at validating the HACCP system in the plant. Validation is subject to the system's compliance with the defined requirements, its effectiveness, and its compliance with the plan targets and the requirements of the legislative authorities. This audit, in addition to examining the implementation of the HACCP, also checks all factors influencing product/process quality, such as environmental factors, pesticide systems, calibration of measuring devices, structural maintenance, internal audits, etc.

A summarizing report is produced on completion of the audit. The report details the faults found during the audit, according to severity (classified as slight/significant incompatibilities). The report is submitted to plant management which is responsible for rectifying incompatibilities identified during the audit. The plant management must also submit incompatibility reports detailing the corrective actions taken in accordance with a time schedule predetermined by the project manager.

The audit report is transferred simultaneously to the certification committee, the members of which include the director of the Department for Inspection of Animal Products, the chairman

of the certification committee, the head veterinarian for exports and imports, the North/South regional veterinarian, and the HACCP project manager. The committee meets to discuss the results of the audit, and has the authority to validate the HACCP system in the plant. The committee is also authorized to delay or prevent the validation of a plan and to demand clarifications/additional activities aimed at determining the quality of the plan prior to final authorization.

Follow-up audits are performed in every authorized plant twice a year following validation of the HACCP system. The aim of the audit is to ensure that the plants implement and maintain the HACCP system and operate according to the requirements.

The veterinary inspection must include routine supervision and ensure proper implementation of the HACCP system. Such supervision will be performed and aided by ongoing verification activities.

Ongoing Verification Activities

The aim of these activities is to verify the proper and effective implementation of the HACCP system (as defined/anticipated by us).

The verification activities include the following subjects:

- Calibration of the measuring instruments used for monitoring (at least once a week).
- Direct observation of the monitoring activities and corrective actions.
- Daily review of forms (including the signature of the person in charge).

The verification activities may include samples of products for microbiological and other tests.

The quality assurance system in the plant is responsible for verifying the monitoring activities, corrective action and documentation and for performing the actual verification.

The inspecting veterinarian is responsible for verifying (independent of the control system) the monitoring activities, corrective action, documentation and verification activities performed by the quality assurance system at the plant.

2. Method

The inspecting veterinarian must verify the implementation of the HACCP system in the plant on a daily basis. The nature of the verification activity and the critical control point on which the verification is performed are subject to the veterinarian's discretion. However, he/she must make sure that these tests are planned in such a way as to ensure that all the plan indices are reviewed every week/month!!

The results of the verification are to be documented in a weekly verification follow-up form (see Appendix A), which is retained in the inspecting veterinarian's office for two years, for follow-up and auditing purposes.

If the inspecting veterinarian identifies discrepancies between that defined in the HACCP plan and that implemented in reality, he/she must inform the quality assurance manager and/or plant manager of the irregularity.

If the irregularity repeats itself constantly, and/or is severe, and in the inspecting veterinarian's opinion, endangers public health, the inspecting veterinarian will immediately notify the plant management of the matter and will oblige it to urgently inform him/her of the corrective actions that it intends to take to correct the irregularity. The inspecting veterinarian's report will be transferred to the plant's management in writing, in accordance

with the format detailed in Appendix B. The plant management response to this application will also be furnished in writing, according to the format detailed in Appendix C, and no later than 24 hours from receipt of the inspecting veterinarian's report regarding the irregularity.

3. Date of Validity

The directives contained in this procedure sheet will come into effect as of October 1, 2000.


Dr. A. Nili

Director
Control of Animal Products

Distribution:

Inspecting veterinarians at slaughter houses and plants authorized to export.

North-south district veterinarians

HACCP project manager

APPENDIX A

Weekly Follow-Up Form for Verification of the HACCP System by the Inspecting Veterinarian

For the week beginning: _____

Date	Verification Activity	Documentation (referral to record in control form)	Comments

Signature of Inspecting Veterinarian: _____

APPENDIX B

Date: _____

To
Mr. _____
Manager, _____ plant

Dear Mr. _____

Re: Significant Discrepancy in Implementation of the HACCP System

As you know, your plant operates an HACCP system which undergoes a continual process of verification. On _____, I found a significant discrepancy in implementation of the system. Below is a description of the discrepancy:

You are requested to instruct your representative to urgently examine the causes of this discrepancy and to take the measures required to bring the HACCP system under control no later than _____ (day) _____ (hour).

Please inform me of the actions you have ordered taken to rectify this matter.

Inspecting Veterinarian
Dr. _____

Copy:
HACCP Project Manager
Regional Veterinarian
Quality Assurance Manager

APPENDIX C

Date: _____

To
Dr. _____
Inspecting veterinarian at the _____ plant

Dear Dr. _____

Re: Significant Discrepancy in Implementation of the HACCP System
Your letter dated: _____

Below, please find details of the corrective actions taken following your letter:

As a result of these actions, the HACCP system is once again functional.

Mr. _____
Plant Manager

Copy:
HACCP Project Manager
Regional Veterinarian
Quality Assurance Manager

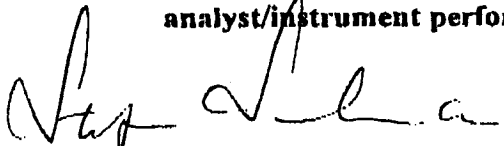
STATE OF ISRAEL

Ministry of Agriculture and Rural Development,
Veterinary Services and Animal Health
Kimron Veterinary Institute, P.O.B 12, Beit-Dagan, 50250.

Dr. Eliezer Nili
Head, Animal Product Control
Ministry of Agriculture/Veterinary Services
Beit Dagan 50250
Israel

Re: Audition report by the USDA concerning the National Residue Control Laboratory, Israel

- 1. Intralaboratory check sample program was revised to comply with the requirements of the USDA/FSIS.**
- 2. Polychlorinated biphenyls (PCB's) were not included in the monitoring program year 2000 (as indicated in the answer of Dr. Nili citing Mr. Mark Manis, Director, International Policy Division/FSIS). Therefore, check samples concerning this group of compounds were not performed.**
- 3. Information in the Laboratory Quality Assurance record books:**
 - a. In the process of revision of the Quality Assurance systems in the National Residue Control Laboratory, the Laboratory now keeps records of all relevant information concerning standard solution/reagents/media.**
 - b. The National Residue Control Laboratory is presently in process to gain ISO 17025 accreditation. In line with this process the Laboratory have appointed a supervisor and a Quality Assurance officer. These changes are also reflected in laboratory procedures such as control of the preparation of standard solutions.**
 - c. Corrective action reports have now been integrated to the Quality system of the Laboratory and, consequently, such report is now filed for every unacceptable analyst/instrument performance.**



Stefan Soback, DVM, PhD

Head, National Residue Control Laboratory